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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/184,572	11/02/1998	LISA MCKERRACHER	12552-002001	4396

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/184,572	MCKERRACHER ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/16/07*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *N/A* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 24 May 2007 has been entered.

Response to Amendment

The amendment filed on 24 May 2007 have been received and entered in full. Following the amendment, claims 25-29, 43 and 45-47 remain pending in the instant application.

Claims 25-29 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in Paper filed on 13 March 2000.

Claims 43 and 45-47 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

This application contains claims 25-29 drawn to an invention nonelected with traverse in Paper filed on 13 March 2000. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 16 July 2007 is enclosed in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varon et al. (cited previously) in view of Kamata et al. (cited previously).

The Varon et al. reference teaches that neurotrophic factors are well recognized for their important function on developing neurons of the PNS, and that said factors were previously proposed to play additional and equally important roles in the CNS. The Varon et al. reference teaches that much less attention has been given to the involvement of neurotrophic factors in CNS regenerative processes (p.473). The reference further teaches various model systems utilizing *in vivo* administration of NGF to promote neuronal outgrowth in the CNS in a spinal cord injury model. The reference teaches infusion of NGF in a pharmaceutical carrier via a continuous infusion device (pharmaceutical delivery system) at a site of surgery, which resulted in dramatically enhanced sensory fiber elongation into the injury site (in an amount effective to suppress inhibition of neuronal growth; pp.477-478).

Upon reading the disclosure of the Varon et al. reference, the skilled artisan would have recognized the desirability of developing improved methods of treating traumatic spinal cord injury. Furthermore, the Kamata et al. reference teaches chick

dorsal root ganglia (DRG) induced nerve outgrowth via administration of C botulinum C3 exoenzyme ADP-ribosyltransferase (CART) that is at least as effective as DRG outgrowth induced via the neurotrophic factor NGF (entire document, e.g., abstract, pp. 424-425 under the heading *Effects of C3 exoenzyme on the morphology of cultured cells* and p. 427, lines 2-23). Kamata et al., conclude from their studies that C3 exoenzyme is a neurotrophic agent. As evidenced by the prior art, the skilled artisan would have known that CART is a neurotrophic factor that is at least as effective as NGF and that neurotrophic factors are useful in providing neurite outgrowth in spinal cord injury. Thus, it would have been obvious to the person of ordinary skill to try methods of increasing neurite regeneration in the CNS via administration of CART to a patient after spinal cord injury in an attempt to provide an improved method of treating SCI. This is because the artisan has good reason to pursue the known options within his or her technical grasp. It is noted that although the prior art references do not necessarily address the claimed cellular functions of CART, e.g., "which antagonist, when scrape loaded into PC12 cells in vitro, produces outgrowth of PC 12 cell neurites, said PC 12 cells being plated on a growth inhibitory substrate selected from the group consisting of myelin and myelin-associated glycoprotein substrate," these are nonetheless inherent to CART. Applicants are reminded that chemical compounds and their properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA1963)), as are their processes and yields (In re Von Schickh, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)).

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varon et al. (cited previously) in view of Kamata et al. (cited previously), further in view of U.S. Patent No. 5,134,121 to Mobley et al.

The Varon et al. reference and the Kamata et al. reference teach as set forth above. Upon reading the disclosure of the Varon et al. reference, the skilled artisan would have recognized the desirability of developing improved methods of treating traumatic spinal cord injury. Furthermore, the Mobley et al. patent teaches NGF and NGF variants (including fragments of NGF) that are useful in the treatment of multiple neurological diseases through promotion of neurite outgrowth (cols. 2, 3, 6-7 and 16-18). The Mobley et al. patent further teaches that a suitable assay to screen for such molecules is via assessing the ability of a molecule to promote neuronal outgrowth in cultured dorsal root ganglia cultures (see Bioassay with dorsal root ganglia neurons, cols. 19-20). As evidenced by the prior art, the skilled artisan would have known that CART is a neurotrophic factor that is at least as effective as NGF and that neurotrophic factors and their fragments are useful in providing neurite outgrowth in spinal cord injury. Thus, it would have been obvious to the person of ordinary skill to try methods of increasing neurite regeneration in the CNS via administration of CART functional fragments to a patient after spinal cord injury in an attempt to provide an improved method of treating SCI. This is because the artisan has good reason to pursue the known options within his or her technical grasp.

In the reply filed 24 May 2007, Applicants' argues that there is no motivation to

combine the references. Applicants assert that the Kamata et al. reference does not suggest using CART in any clinical setting or that CART might be involved in neuronal regeneration. Applicants assert said reference teaches away from the claimed invention since it teaches very high doses of CART. Regarding the Varon et al. reference, Applicants allege that the reference does not suggest that CART can be used for an agent of spinal cord repair. Regarding the '121 patent, Applicants allege that there is no disclosure or suggestion of treating spinal cord injury with NGF or anything else.

Applicants' arguments have been fully considered and are not found persuasive. As set forth above, it would be obvious to combine the disclosures of the Varon et al. reference, the Kamata et al. reference and the '121 patent to arrive at the claimed invention. It is irrelevant that the Kamata et al. reference teaches very high doses of CART; the reference still refers to CART as a neurotrophic agent. Therefore, the artisan would recognize the protein as therapeutically useful. Applicants are reminded that it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art See In *re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore regarding Applicants' assertion that there is no motivation to combine the references under 35 U.S.C. 103(a), it is noted that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. &

Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf). Rather, the rationale for the instant finding of obviousness is that the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
16 August 2007

LORRAINE SPECTOR
PRIMARY EXAMINER